Health Canada Santé Canada

Guidance Document

Cancellation of a Drug Identification Number (DIN) and Notification of Discontinuation of Sales

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Canada

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Document Change Log

Date	Change	Location (section, paragraph)	Nature of and/or Reason for Change	Date of Implementation
2018/06/13	Expanded Scope to include drugs listed in Schedule C of the Regulations	S3	Regulations Amending the Food and Drug Regulations (DIN Requirements for Drugs Listed in Schedule C to the Food and Drug Act that are in Dosage Form)	2018/06/13
2018/06/13	Amended definition of Discontinue and removed definition of Authorization Holder or Drug Authorization Holder	S5	Regulations Amending the Food and Drug Regulations (DIN Requirements for Drugs Listed in Schedule C to the Food and Drug Act that are in Dosage Form)	2018/06/13
2018/06/13	Amended Regulatory text	S6.1	Regulations Amending the Food and Drug Regulations and the Regulations Amending the Food and Drug Regulations (DIN Requirements for Drugs Listed in Schedule C to the Food and Drug Act that are in Dosage Form)	2018/06/13
2018/06/13	Amended Regulatory text	S6.2, S6.3	Regulations Amending the Food and Drug Regulations (DIN Requirements for Drugs Listed in Schedule C to the Food and Drug Act that are in Dosage Form)	2018/06/13
2018/06/13	Clarification on reporting a period of 12 months without sale due to low market demand	S6.3	To improve clarity	2018/06/13
2018/06/13	Added process for reporting a 12 month period without sale on the Annual Drug Notification and Amended Regulatory text	S6.3.1, S6.3.2	New reporting requirements in the Regulations Amending the Food and Drug Regulations (DIN Requirements for Drugs Listed in Schedule C to the Food and Drug Act that are in Dosage Form) and revised wording	2018/06/13
2018/06/13	Clarification in wording	S7	To align with the Guidance Document Reporting Adverse Reactions to Marketed Health Products	2018/06/13

2018/06/13	Reordering of the Appendices	Appendices A, B, C	To improve readability	2018/06/13
2018/06/13	Change to the description for the Dormant status	Appendix A	To improve clarity	2018/06/13

FOREWORD

Guidance documents are meant to provide assistance to industry and health care professionals on how to comply with governing statutes and regulations. Guidance documents also provide assistance to staff on how Health Canada mandates and objectives should be implemented in a manner that is fair, consistent and effective.

Guidance documents are administrative instruments not having force of law and, as such, allow for flexibility in approach. Alternate approaches to the principles and practices described in this document may be acceptable provided they are supported by adequate justification. Alternate approaches should be discussed in advance with the relevant program area to avoid the possible finding that applicable statutory or regulatory requirements have not been met.

As a corollary to the above, it is equally important to note that Health Canada reserves the right to request information or material, or define conditions not specifically described in this document, in order to allow the Department to adequately assess the safety, efficacy or quality of a therapeutic product. Health Canada is committed to ensuring that such requests are justifiable and that decisions are clearly documented.

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1. Introduction

A Drug Identification Number (DIN) serves as an identifier of a drug and its associated characteristics. The assignment of a DIN indicates that a drug has undergone a successful Health Canada review process and is currently authorized for sale in Canada. The issuance of a Notice of Compliance (NOC) following a successful review is also required for the sale of drugs that are regulated under Part C, Division 8 of the Food and Drug Regulations (the Regulations). All authorized DIN products are listed on the Drug Product Database (DPD) online, as either approved, marketed, dormant or cancelled (refer to Appendix A for a list of all available online statuses). As the information contained on the DPD online is accessed by different parties such as patients, healthcare professionals, pharmaceutical companies, and provincial and territorial governments, it is crucial for the health and safety of all Canadians that this information is accurate and up to date.

2. Purpose

The purpose of this guidance document is to provide assistance in interpreting sections C.01.014.6 and C.01.014.7 of the Regulations for the cancellation of a DIN and the notification to Health Canada of the discontinuation of the sale of a drug. These guidelines are designed to facilitate proper compliance by the manufacturers and to enhance consistency in the application of the regulatory requirements.

3. Scope

This guidance document applies to all drugs which have been issued a DIN under section C.01.014.2 (1) of the Regulations. This includes all prescription and non-prescription drugs for human and veterinary use as well as drugs listed in Schedule C (radiopharmaceuticals) and disinfectants.

Note: This guidance document covers the mandatory reporting of a discontinuation of the sale of a product that has a DIN assigned by Health Canada, under section C.01.014.7 of the Regulations. Manufacturers must also comply with the requirements of sections C.01.014.8 to C.01.014.10 and C.01.014.71 of the Regulations to report drug shortages and discontinuations of the sale of drugs included in Schedules I, II, III, IV or V to the Controlled Drugs and Substances Act, prescription drugs, drugs listed in Schedules D and C to the Food and Drug Act (the Act) and drugs that may be sold without a prescription, but are administered only under a practitioner's supervision on the reporting website, and to notify Health Canada of the interruption of sales of a drug (12 months without sale). Refer to the document Guide to Reporting Drug Shortages and Discontinuations for more information.

4. Policy objectives

The policy objectives that guide the regulatory authority for DIN cancellation and the requirement for reporting drug discontinuation to Health Canada are as follows:

- to provide the public with timely, reliable and accurate information on the availability of drugs in Canada; and
- to help protect the health and safety of Canadians from the sale of unsafe drugs

These objectives should be considered when complying with the Regulations including when interpreting the regulatory requirements for specific situations.

5. Definitions

Discontinue (as per section C.01.001 (1) of the Regulations), means, in respect of the sale of a drug by the manufacturer to whom a document was issued under subsection C.01.014.2(1) that sets out the drug identification number assigned for the drug, to permanently cease the sale of the drug.

Discontinuation date

- If a manufacturer is selling a drug and decides to discontinue its sale, the date of the discontinuation is the date of the last sale by the manufacturer.
- If a manufacturer has temporarily stopped selling a drug and then decides to discontinue its sale later, the discontinuation date is the date on which the decision to discontinue the sale was made.

Drug Identification Number (DIN) is a computer-generated eight digit number assigned by Health Canada to a drug prior to being marketed in Canada. It identifies all drugs under the Regulations sold in a dosage form in Canada and is located on the label of prescription and non-prescription drugs that have been evaluated and authorized for sale in Canada. A DIN uniquely identifies the following product characteristics: manufacturer; product name; active ingredient(s); strength(s) of active ingredient(s); pharmaceutical form; route of administration.

Expiration date (as per section C.01.001 (1) of the Regulations), means

(a) in the case of a drug in dosage form, the earlier of the following dates, expressed at minimum as a year and month:

(i) the date up to and including which the drug maintains its labelled potency, purity and physical characteristics, and

(ii) the date after which the manufacturer recommends that the drug not be used; and

(b) in the case of an active ingredient, whichever of the following dates is applicable, expressed at minimum as a year and month:

(i) the retest date, or

(ii) the date after which the manufacturer recommends that the active ingredient not be used.

Lot number (as per section A.01.010 of the Regulations), means any combination of letters, figures, or both, by which any food or drug can be traced in manufacture and identified in distribution.

Manufacturer or Distributor (as per section A.01.010 of the Regulations), means a person, including an association or partnership, who under their own name, or under a trade, design or word mark, trade name or other name, word or mark controlled by them, sells a food or drug. For the purpose of this document, a manufacturer is a DIN Holder.

6. Guidance for implementation

The next part of this document provides:

- the exact text of the relevant sections of Part C, Division 1 of the Regulations;
- Health Canada's interpretation of these sections;
- information on their operational implementation; and
- guidance on how companies can comply with the requirements.

6.1 Section C.01.014.6 Cancellation of a Drug Identification Number (DIN)

Section C.01.014.6 outlines the circumstances under which Health Canada has the authority to cancel a DIN.

"C.01.014.6

(1) The Minister shall cancel the assignment of a drug identification number for a drug if

(a) the person to whom a document was issued under subsection C.01.014.2(1) that sets out the drug identification number advises under section C.01.014.7 that they discontinued the sale of the drug; or

(c) the Minister determines that the product for which the drug identification number has been assigned is not a drug.

(2) The Minister may cancel the assignment of a drug identification number for a drug if

(a) the manufacturer to whom a document was issued under subsection C.01.014.2(1) that sets out the drug identification number contravenes section C.01.014.5;

(b) the manufacturer to whom a document was issued under subsection C.01.014.2(1) that sets out the drug identification number has been notified under section C.01.013 that the evidence that they submitted with respect to the drug is not sufficient; or

(c) the drug is a new drug in respect of which the notice of compliance has been suspended under section C.08.006.

(3) The Minister may cancel the assignment of a drug identification number for a drug if, after he or she has, under section 21.31 of the Act, ordered the holder of a therapeutic product authorization referred to in subparagraph C.01.052(1)(b)(i) or (iii) to conduct an assessment of the drug in order to provide evidence establishing that the benefits associated with the drug outweigh the risks of injury to health,

(a) the holder fails to comply with the order; or

(b) the holder complies with the order but the Minister determines that the results of the assessment are not sufficient to establish that the benefits associated with the drug outweigh the risks of injury to health.

(4) For greater certainty, the Minister's power to cancel the assignment of a drug identification number

(a) under paragraph (2)(b) is not affected by his or her power to cancel the assignment of such a number under subsection (3); and

(b) under subsection (3) is not affected by his or her power to cancel the assignment of such a number under paragraph (2)(b)."

6.1.1 Section C.01.014.6 (1) (a): Cancellation Due to Discontinuation of Sale

"The Minister shall cancel the assignment of a drug identification number for a drug if the person to whom a document was issued under subsection C.01.014.2(1) that sets out the drug identification number advises under section C.01.014.7 that they discontinued the sale of the drug."

The cancellation of the DIN is initiated by the Minister further to the receipt of a sale discontinuation notification from a manufacturer under section C.01.014.7 of the Regulations.

Once received, the DIN cancellation date will be added to the DPD online database generally within a week of receipt. If the product has never been marketed the status of the drug will be updated on the DPD online to "Cancelled (Pre-Market)". If the product was marketed the status of the drug on the DPD online will be updated to "Cancelled (Post-Market)". The Office of Submissions and Intellectual Property (OSIP) will send confirmation to the manufacturer or the designated representative that the DIN cancellation has been processed.

For products that were marketed before the cancellation of the DIN, the expiry date of the last lot distributed in Canada, the lot number, and the DIN cancellation date will be posted on the DPD online. For further information on the consequences of a DIN Cancellation, please refer to section 7 below.

6.1.2 Section C.01.014.6 (1) (c): Cancellation as Product is Not a Drug

"The Minister shall cancel the assignment of a drug identification number for a drug if the Minister determines that the product for which the drug identification number has been assigned is not a drug."

The cancellation of the DIN is initiated by the Minister when it is determined that the corresponding product is not a drug under the Regulations. In this scenario, Health Canada will explain to the manufacturer in writing that the product is being reclassified and will no longer be regulated as a drug under the Regulations. The manufacturer will be provided further information regarding the date on which the product's status will be changed and the DIN(s) cancelled. If applicable, information will be provided as to which set of Regulations the product will be subject to in order for the product to be marketed on the Canadian market.

Following the reclassification of the product, Health Canada will cancel the DIN and remove the product from the DPD online. A confirmation of the cancellation of the DIN will be sent to the manufacturer.

6.1.3 Section C.01.014.6 (2) (a): Cancellation Due to Failure to Provide Annual Notification

"The Minister may cancel the assignment of a drug identification number for a drug if the manufacturer to whom a document was issued under subsection C.01.014.2(1) that sets out the drug identification number contravenes section C.01.014.5."

Every year manufacturers must provide a signed copy of the Annual Drug Notification Form (ADNF) to Health Canada. The ADNF serves as an attestation that all the information previously provided by the manufacturer with respect to the drug is correct, and to provide any related updates to Health Canada.

Each year before the first day of October, the OSIP will contact all manufacturers who have failed to return a signed copy of the ADNF to remind them of their regulatory obligations.

If by the first of October the ADNF has not been received by Health Canada, as per section C.01.014.5 of the Regulations, the Director may initiate the cancellation of the DIN(s). A written final notice will be provided to the manufacturer to inform them that their DIN(s) will be cancelled in accordance with section C.01.014.6 (2) (a) of the Regulations and that they can no longer sell the drug as per C.01.014 (1) of the Regulations.

Health Canada will subsequently update the status of the drug on the DPD online to "Cancelled (Unreturned Annual)" and a confirmation of the cancellation of the DIN will be sent to the manufacturer.

6.1.4 Section C.01.014.6 (2) (b): Cancellation due to Concerns Regarding Safety and Efficacy

"The Minister may cancel the assignment of a drug identification number for a drug if the manufacturer to whom a document was issued under subsection C.01.014.2(1) that sets out the drug identification number has been notified under section C.01.013 that the evidence that they submitted with respect to the drug is not sufficient."

The cancellation of the DIN may be initiated by the Minister when a manufacturer fails to provide Health Canada with sufficient evidence regarding the safety and effectiveness of the drug for its recommended use.

Prior to the cancellation of the DIN, in accordance with Section C.01.013(1) of the Regulations, the manufacturer will be requested in writing by the Minister to submit evidence by a specified date. Under section C.01.013(2), if the evidence submitted is not sufficient, the Minister will notify the manufacturer in writing and the Minister may determine that a DIN cancellation is warranted.

Following the determination that a DIN cancellation is warranted, a written notice will be provided to the manufacturer to inform them that their DIN is being cancelled in accordance with section C.01.014.6.2 (b) of the Regulations and that they can no longer sell the drug as per C.01.014(1) of the Regulations. For further information on the consequences of a DIN Cancellation, please refer to section 7 below.

Health Canada will subsequently update the status of the drug on the DPD and a confirmation of the cancellation of the DIN will be sent to the manufacturer. The new status of the DIN "Cancelled (Safety Issue)" will be reflected on the DPD online the following day.

6.1.5 Section C.01.014.6 (2) (c): Cancellation following the suspension of a Notice of Compliance (NOC)

"The Minister may cancel the assignment of a drug identification number for a drug if the drug is a new drug in respect of which the notice of compliance has been suspended under section C.08.006."

As outlined by section C.08.002 (1) (c) of the Regulations no person can sell a drug with a suspended NOC. This prohibition on sale applies to the manufacturers and to all other parties such as wholesalers, retailers, pharmacists and medical practitioners and is effective on the date the NOC is suspended.

Following the suspension of the NOC, the minister may cancel the DIN in accordance with section C.01.014.6 (2) (c) of the Regulations. A written notice will be provided to the manufacturer if the intent is to cancel the DIN.

Further to the decision to cancel the DIN, Health Canada will subsequently update the status of the drug on the DPD and a confirmation of the cancellation of the DIN will be sent to the manufacturer. The new status of the DIN "Cancelled (Safety Issue)" will be reflected on the DPD online the day following notification that the DIN has been cancelled.

6.1.6 Section C.01.014.6 (3): Cancellation related to the order to conduct an assessment

To enable Health Canada to regulate a drug more efficiently and effectively throughout its life cycle, the Minister has the power to order the therapeutic authorization holder to conduct assessments, compile information, conduct tests or studies or monitoring of experience in respect of the therapeutic product and provide the Minister with the results under sections 21.31 of the Food and Drug Act.

For more information on the Minister's power to require assessment under Section 21.31 of the Act and power to require test, studies, etc., please refer to the guidance: Amendments to the Food and Drugs Act: Guide to New Authorities (power to require and disclose information, power to order a label change and power to order a recall) (https://www.canada.ca/en/health-canada/services/drugs-health-products/legislation-guidelines/amendments-food-drugs-act-guide-new-authorities-power-require-disclose-information-power-order-label-change-power-order-recall.html).

6.1.6.1 Section C.01.014.6 (3)(a): Cancellation following the failure to comply with the order to conduct an assessment and provide the results

"The Minister may cancel the assignment of a drug identification number for a drug if, after he or she has, under section 21.31 of the Act, ordered the holder of a therapeutic product authorization referred to in subparagraph C.01.052(1)(b)(i) or (iii) to conduct an assessment of the drug in order to provide evidence establishing that the benefits associated with the drug outweigh the risks of injury to health, the holder fails to comply with the order."

If the therapeutic product authorization holder fails to comply with the order under section 21.31 to provide the requested information, the Minister may cancel the DIN in accordance with section C.01.014.6 (3)(a). A written notice will be provided to the therapeutic authorization holder if the intent is to cancel the DIN.

Further to the decision to cancel the DIN, Health Canada will subsequently update the status of the drug on the DPD and a confirmation of the cancellation of the DIN will be sent to the manufacturer. The new status of the DIN "Cancelled (Safety Issue)" will be reflected on the DPD online the day following notification that the DIN has been cancelled.

6.1.6.2 Section C.01.014.6 (3)(b): Cancellation following the examination of the results of an assessment

"The Minister may cancel the assignment of a drug identification number for a drug if, after he or she has, under section 21.31 of the Act, ordered the holder of a therapeutic product authorization referred to in subparagraph C.01.052(1)(b)(i) or (iii) to conduct an assessment of the drug in order to provide evidence establishing that the benefits associated with the drug outweigh the risks of injury to health, the holder complies with the order but the Minister determines that the results of the assessment are not sufficient to establish that the benefits associated with the drug outweigh the risks of injury to health."

If following the assessment of the information provided in response to an order under section 21.31 of the Food and Drug Act, it is determined that the risks to injury or health outweigh the benefits, the Minister may cancel the DIN in accordance with C.01.014.6 (3)(b). A written notice will be provided to the therapeutic authorization holder if the intent is to cancel the DIN.

Further to the decision to cancel the DIN, Health Canada will subsequently update the status of the drug on the DPD and a confirmation of the cancellation of the DIN will be sent to the manufacturer. The new status of the DIN "Cancelled (Safety Issue)" will be reflected on the DPD online the day following notification that the DIN has been cancelled.

6.1.7 Section C.01.014.6 (4)

"For greater certainty, the Minister's power to cancel the assignment of a drug identification number

(a) under paragraph (2)(b) is not affected by his or her power to cancel the assignment of such a number under subsection (3); and

(b) under subsection (3) is not affected by his or her power to cancel the assignment of such a number under paragraph (2)(b)."

The Minister has the ability cancel a DIN when there are concerns in respect to safety under both C.01.14.6 (2)(b) and C.01.14.6 (3) of the Regulations, however these section are not dependent on each other.

One or both of the sections may be applied when determining if the cancellation of DIN is warranted.

6.2 Section C.01.014.7 Discontinuation Notification

"The manufacturer to whom a document was issued under subsection C.01.014.2(1) that sets out the drug identification number assigned for a drug shall, within 30 days after the day on which they discontinue the sale of the drug, submit the following information to the Minister:

(a) the drug identification number assigned for the drug;

(b) the date on which the manufacturer discontinued the sale of the drug; and

(c) the latest expiration date of the drug that the manufacturer sold and the lot number of that drug."

This section of the Regulations allows the Department to ensure that the drug information provided on the Department's website is accurate and up to date, while maintaining regulatory oversight of drugs available on the Canadian market until their expiry dates.

As noted earlier in the Definition section, discontinue (as per section C.01.001 (1) of the Regulations), means, in respect of the sale of a drug by the manufacturer of the drug, to permanently cease the sale of the drug.

The manufacturer must notify Health Canada within 30 calendar days of the date the sale of the drug was discontinued.

The sale discontinuation notification from the manufacturer[1] should be in writing on company letterhead and signed by an authorized official. It must have the following information:

- The DIN of the discontinued product;
- The discontinuation date of the product; and
- The lot number and expiry date of the last lot sold by the manufacturer.

The sale discontinuation notification should be sent electronically.

1. Documents for submissions in "non-eCTD electronic-only" format must be sent by one of the following ways:
    - by email to HC.DIN.SC@canada.ca,
    - on electronic media to:

      Office of Submissions and Intellectual Property (OSIP)
      Finance Building
      101 Tunney's Pasture Driveway
      Address Locator: 0201A1
      Ottawa, Ontario
      K1A 0K9
2. Documents for submissions in eCTD format must be sent via the Common Electronic Submissions Gateway (CESG).

For more information on how to submit transactions to Health Canada, please refer to section "Transmission of Electronic Data" in the guidance documents:

- Preparation of Drug Regulatory Activities in Electronic Common Technical Document Format, for regulatory activities in eCTD format; and
- Preparation of Drug Regulatory Activities in the "Non-eCTD Electronic-Only" Format, for regulatory activities in "non-eCTD electronic-only" format.

When Health Canada receives the notification of discontinuations, the Department will proceed to cancel the DIN as described in Section 6.1.1 of this document.

6.3 Sections C.01.014.5(1)(a)(ii) and C.01.014.71 - 12 months without sale notification

For all marketed products, manufacturers are required to submit a notification to Health Canada when a product has not been sold for a period of 12 consecutive months. The timing of this reporting is determined by the type of product and is outlined in Sections 6.3.1 and 6.3.2 of this document.

In the case of a product with no sales due to low market demand, if the manufacturer maintains an inventory of the product and the product is still available for purchase on the Canadian market, the manufacturer is still required to report the DIN as Dormant as per Section C.01.014.71 and Subsection C.01.014.5(1)(a)(ii) of the Regulations; however, in such circumstances, Health Canada may choose to keep the status of the DIN as

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[1] Manufacturers may have a third party, such as an importer or designated representative, act on their behalf and submit the notification

marketed in the DPD online in order to avoid unintended impact on treatment plans. If there are some sales, there is no obligation to notify under C.01.014.71 or C.01.014.5(1)(a)(ii).

If subsequent to notifying Health Canada of the period without sale, the manufacturer determines that they will not resume sale of the product on the Canadian market they must submit a sale discontinuation notification as outlined in Section 6.2 of this document.

If subsequent to notifying Health Canada of the period without sale, the manufacturer determines that they will resume sale of the product on the Canadian market they must submit, within 30 days after commencing sale of the drug, a signed and dated Drug Notification Form (DNF) in accordance with section C.01.014.72 of the Regulations.

6.3.1 Section C.01.014.5(1)(a)(ii) Reporting 12 months without sale on the Annual Drug Notification Form

"C.01.014.5(1)

The manufacturer to whom a document was issued under subsection C.01.014.2(1) that sets out the drug identification number assigned for a drug shall, annually before the first day of October and in a form established by the Director, provide the Director with a notification that is signed by them and that

(a) indicates whether any of the following circumstances apply in respect of the drug

(ii) the manufacturer has not sold the drug in Canada for a period that is greater than 12 months and a portion of that period covered by the notification"

For all marketed products, which have been issued a DIN under subsection C.01.014.2(1) of the Regulations, the manufacturer must indicate on the ADNF if the product has not been sold on the Canadian market for a period of 12 consecutive months.

Instructions on how to complete and submit the ADNF are included with the Annual Drug Notification Package sent to the manufacturer each year by Health Canada.

Once the notification is received by Health Canada, the status of the drug will be updated on the DPD online to "Dormant" using the date of the signed ADNF.

Additional notification requirements apply to certain products. Please refer to Section 6.3.2 for additional reporting requirements.

6.3.2 Section C.01.014.71 Reporting 12 months without sale within 30 days

The following drugs for human use as identified in section C.01.014.8 of the Regulations have additional reporting requirements:

- drugs included in Schedules I, II, III, IV or V to the Controlled Drugs and Substances Act (http://laws-lois.justice.gc.ca/eng/acts/C-38.8/)
- prescription drugs (https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/prescription-drug-list/list.html)
- drugs listed in Schedules D and C to the Act (http://laws.justice.gc.ca/eng/acts/F-27/), and
- drugs that may be sold without a prescription, but are administered only under a practitioner's supervision (e.g. hemodialysis solutions, pre-filled syringes with epinephrine for severe allergic reactions, magnetic resonance imaging (MRI) contrast agents).

"C.01.014.71

If a period of 12 months has elapsed since the day on which the manufacturer to whom a document was issued under subsection C.01.014.2(1) that sets out the drug identification number assigned for a drug

defined in section C.01.014.8 last sold the drug, the manufacturer shall so notify the Minister in writing within 30 days after the day on which that period ends."

Manufacturers are required to submit a notification to Health Canada within 30 calendar days after a period of 12 consecutive months that a product has not been sold on the Canadian market. This section allows the Department to ensure that the drug information provided in the DPD online is accurate and up to date. It also assists in maintaining regulatory oversight of drugs that are available on the Canadian market and in responding to drug shortages.

The 12 months without sale notification from the manufacturer should be in writing on company letterhead and signed by an authorized official and should be sent electronically. For instructions on how to submit transactions to Health Canada, please refer to the instructions in section 6.2 of this guidance.

Once the notification is received by Health Canada the status of the drug will be updated on the DPD online to "Dormant".

7. Consequences of the Drug Identification Number (DIN) Cancellation

When the DIN of a drug is cancelled under section C.01.014.6 of the Regulations, no further sales may be made by the manufacturer since C.01.014 (1) of the Regulations prohibits manufacturers from selling drugs without a DIN.

So as not to create undue burden on industry, Health Canada may allow other parties in the downstream chain of distribution such as wholesalers, retailers, pharmacists and medical practitioners to continue to sell or distribute the remaining drug products after the DIN is cancelled, if the expiry date of the drug product lot is not passed and so long as the cancellation of the DIN was not due to health or safety reasons. Products without a valid DIN/NOC cannot be imported.

The manufacturer remains subject to several post-market obligations for its own drug that is distributed prior to the cancellation of the DIN until the expiration of the last lot distributed or the longest time period referred to in the Regulations.

For example, requirements for manufacturers to maintain records adverse drug reactions as per section C.01.020 of the Regulations, and for wholesalers and distributors to keep records as per section C.02.022 of the Regulations are still applicable after the DIN is cancelled. Although the Market Authorization Holder is not obliged to report any new cases of adverse reactions received following the product's discontinuation, Health Canada strongly encourages the reporting of all serious adverse reactions and may request the provision of this information. Additional information on these reporting requirements can be found in the Guidance Document for Industry - Reporting Adverse Reactions to Marketed Health Products.

To illustrate possible consequences of DIN cancellation after the sale of the drug has been discontinued and no safety issue is associated with the cancellation of the DIN[2]:

> A manufacturer discontinues the sale of a drug on February 28th and informs Health Canada on the same day. Health Canada cancels the DIN. However, the drug is currently on the market and the expiry date of the last lot is December 30th.

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[2] Please note that this scenario is illustrative only. Manufacturers should consult the Regulations for the obligations which apply to their particular circumstances.

Wholesalers, retailers, pharmacists and medical practitioners may continue to sell or distribute the drug until December 30th, if there were lots of the drug which were already in their possession before the DIN was cancelled. However an importer cannot continue to import the drugs without an active DIN.

The wholesalers, distributors and importers are still responsible for all the record keeping requirements of the Food and Drug Regulations including C.02.022 of the Regulations for all the lots of the drug that existed on the market, including the ones after the DIN was cancelled (i.e. between February 28th and December 30th). Under section C.02.022 of the Regulations, records shall be retained for one year after the expiration date of the last lot unless the establishment license specifies some other period.

The manufacturer should continue to file the appropriate submission[3] whenever significant updating of the product monograph is required in order to incorporate additions or other changes related to safety (particularly with respect to warnings and precautions, adverse reactions, and route of administration) that may be necessary as a result of newly available information, up until all the lots of the drug that existed on the market have expired.

If Health Canada becomes aware of any risk or non-compliance with respect to a drug with a cancelled DIN, Health Canada will take appropriate actions to mitigate the risk in accordance with the Compliance and Enforcement Policy (POL-0001).

8. Commercial exportation

When a manufacturer, holding a DIN for a drug, discontinues the sale of that drug for consumption in Canada but continues to export the drug, the type of exportation will determine whether the sale of the drug is considered to be discontinued in Canada.

- To export a drug in compliance with the Act and the Regulations without invoking section 37 of the Act, manufacturers require, among other things, an authorization to sell the drug (DIN and/or NOC) since these types of commercial exportations are usually considered sales in Canada. In this case, the exported drug is not considered to be discontinued and manufacturers are not required to send a sale discontinuation notification to Health Canada. The product will continue to appear in the DPD online with the status "Marketed" and the manufacturer remains subject to post-market obligations.
- If a drug which was destined for consumption in Canada is discontinued, but continues to be exported under section 37 of the Act, the drug is considered discontinued in Canada. Manufacturers are exempted from the application of the Act[4] when a drug is exported by invoking section 37 of the Act and the conditions set out in that section have been met. In this case, manufacturers will be required to send a sale discontinuation notification to Health Canada for the drug that has been discontinued. The DIN will be cancelled and the status of the product in the DPD online will be changed to "Cancelled (Post-Market)".

For more information on section 37 of the Act, see Intention to Invoke Section 37 of the Canada Food and Drugs Act for Products Being Exported (https://www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/establishment-licences/intention-invoke-section-37-canada-food-drugs-act-products-being-exported.html).

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[3] Supplement to a New Drug Submission (SNDS), Supplement to an Abbreviated New Drug Submission (SANDS)

[4] Please note that according to s.37(1.1)(b) of the Act, despite section 37(1) of the Act, section 8, subsection 9(1) and section 11 of the Act apply to a drug that is not a natural health product.

Appendices

Appendix A: List of online statuses

- **Approved** refers to an active DIN that has been reviewed and authorized for sale in Canada but has not yet been marketed in Canada.
- **Marketed** refers to an active DIN that is currently being sold in Canada.
- **Dormant** refers to an active DIN that was previously marketed in Canada but for which there have been no sales for a period of at least 12 months.
- **Cancelled (Unreturned Annual)** refers to a DIN that is cancelled due to failure to provide the Annual Notification under Section C.01.014.6 (2) (a) of the Regulations.
- **Cancelled (Safety Issue)** refers to a DIN that is cancelled under
  - Section C.01.014.6 (2) (b) of the Regulations due to failure to provide evidence regarding the safety and effectiveness of a drug, under Section C.01.013 of the Regulations.
  - Section C.01.014.6 (2) (b) of the Regulations following the suspension of and Notice of Compliance of the Regulations or to the suspension of a Notice of Compliance
  - Section C.01.014. 6 (3) (a) of the Regulations following the failure to comply with the order issued under section 21.31 of the Act to conduct an assessment and provide the results
  - Section C.01.014.6 (3) (b) of the Regulations following the examination of the results of an assessment provided in response to an order issued under section 21.31 of the Act
- **Cancelled (Pre-Market)** refers to a DIN that is cancelled before it was ever marketed in Canada.
- **Cancelled (Post-Market)** refers to a DIN that is cancelled further to the discontinuation of the sale by the manufacturer under Section C.01.014.6 (1) (a) of the Regulations.

Appendix B: Glossary

Act (the):
Food and Drugs Act

ADNF:
Annual Drug Notification Form

DIN:
Drug Identification Number

DPD:
Drug Product Database

NOC:
Notice of Compliance

OSIP:
Office of Submissions and Intellectual Property

Regulations (the):
Food and Drug Regulations

Appendix C: References

- Compliance and Enforcement Policy (POL-0001) (https://www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/good-manufacturing-practices/policies-standards/compliance-enforcement-policy-0001.html)
- (Archived) Drug Identification Number (DIN) Enforcement Policy (POL-0040) (https://www.canada.ca/en/health-canada/services/drugs-health-products/compliance-

enforcement/information-health-product/drugs/drug-identification-number-enforcement-directive-0040.html)

- Food and Drugs Act (http://laws-lois.justice.gc.ca/eng/acts/f-27/)
- Food and Drug Regulations (http://laws-lois.justice.gc.ca/eng/Regulations/c.r.c.,_c._870/index.html)
- Guidance Document: Preparation of Drug Regulatory Activities in Electronic Common Technical Document Format (https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/applications-submissions/guidance-documents/common-technical-document/updated-guidance-document-preparation-regulatory-activities-non-ectd-electronic-only-format.html)
- Guidance Document: Preparation of Drug Regulatory Activities in the "Non-eCTD Electronic-Only" Format (https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/applications-submissions/guidance-documents/common-technical-document/updated-guidance-document-preparation-regulatory-activities-non-ectd-electronic-only-format.html)
- Guidance Document: Guide to Reporting Drug Shortages and Discontinuations (https://www.canada.ca/content/dam/phac-aspc/documents/services/publications/drugs-health-products/reporting-drug-shortages-discontinuations/reporting-drug-shortages-discontinuations.pdf)
- Health Canada's Drug Product Database (https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html)
- Intention to Invoke Section 37 of the Canada Food and Drugs Act for Products Being Exported (https://www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/establishment-licences/intention-invoke-section-37-canada-food-drugs-act-products-being-exported.html)